



12-08-06

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PTO/SB/21 (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 09/903,665-Conf. #3102

Filing Date July 13, 2001

First Named Inventor Giancarlo Santus

Art Unit 1614

Examiner Name Frederick F. Krass

Attorney Docket Number 04266/1006895-US2

**ENCLOSURES (Check all that apply)**☒ Fee Transmittal Form☒ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement☐ Certified Copy of Priority Document(s)☐ Reply to Missing Parts/  
Incomplete Application☐ Reply to Missing Parts under  
37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) \_\_\_\_\_☐ Landscape Table on CD☐ After Allowance Communication  
to TC☐ Appeal Communication to Board of  
Appeals and Interferences☐ Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please  
Identify below):3 References attached  
Return Receipt Postcard

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name DARBY &amp; DARBY P.C.

Signature

Printed name Irina E. Vainberg

Date December 6, 2006

Reg. No. 48,008



Application No. (if known): 09/903,665

Attorney Docket No.: 04266/1006895-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. in an envelope addressed to:

MS ~~Missing Parts~~ *Amendment*  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on December 6, 2006  
Date

*Lillian Garcia*  
\_\_\_\_\_  
Signature

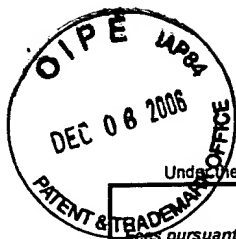
*Lillian Garcia*  
\_\_\_\_\_  
Typed or printed name of person signing Certificate

N/A  
Registration Number, if applicable

(212) 527-7700  
Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Supplemental Information Disclosure Statement (5 pages)  
IDS (Citation) by Applicant (9 References, 3 attached) (1 page)  
Transmittal (1 page)  
Fee Transmittal (1 page)  
Check in the amount of \$180.00 12807



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<b>Effective on 12/08/2004.</b> Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).		<b>Complete if Known</b>		
<b>FEE TRANSMITTAL</b> <b>For FY 2006</b>		Application Number	09/903,665-Conf. #3102	
		Filing Date	July 13, 2001	
		First Named Inventor	Giancarlo Santus	
		Examiner Name	Frederick F. Krass	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Art Unit	1614	
TOTAL AMOUNT OF PAYMENT	(\$)	180.00	Attorney Docket No.	04266/1006895-US2

**METHOD OF PAYMENT (check all that apply)**

☒ Check    ☐ Credit Card    ☐ Money Order    ☐ None    ☐ Other (please identify): \_\_\_\_\_

☐ Deposit Account    Deposit Account Number: 04-0100    Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below    ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17    ☒ Credit any overpayments

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>
_____	_____	_____	_____	<u>Fee (\$)</u>
HP = highest number of total claims paid for, if greater than 20.				<u>Fee Paid (\$)</u>
<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	
_____	_____	_____	_____	
HP = highest number of independent claims paid for, if greater than 3.				

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
_____	_____	_____	_____	_____
_____ - 100 = _____ /50 _____ (round up to a whole number) x _____ = _____				

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement	180.00

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	48,008
Name (Print/Type)	Irina E. Vainberg	Telephone	(212) 527-7634
		Date	December 6, 2006



Docket No.: 04266/1006895-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Giancarlo Santus et al.

Application No.: 09/903,665

Confirmation No.: 3102

Filed: July 13, 2001

Art Unit: 1614

For: THERAPEUTIC COMPOSITIONS FOR  
INTRANASAL ADMINISTRATION WHICH  
INCLUDE KETOROLAC

Examiner: Frederick F. Krass

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Supplemental Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:  
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☒ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes “i” and “ii” below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☒ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

{W:\04266\1006895us2\00926791.doc 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1041 1042 1043 1044 1045 1046 1047 1048 1049 1050 1051 1052 1053 1054 1055 1056 1057 1058 1059 1060 1061 1062 1063 1064 1065 1066 1067 1068 1069 1070 1071 1072 1073 1074 1075 1076 1077 1078 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089 1090 1091 1092 1093 1094 1095 1096 1097 1098 1099 1100 1101 1102 1103 1104 1105 1106 1107 1108 1109 1110 1111 1112 1113 1114 1115 1116 1117 1118 1119 1120 1121 1122 1123 1124 1125 1126 1127 1128 1129 1130 1131 1132 1133 1134 1135 1136 1137 1138 1139 1140 1141 1142 1143 1144 1145 1146 1147 1148 1149 1150 1151 1152 1153 1154

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

- ☒ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☐ 5. Other information being provided for the examiner's consideration follows:

[A/An \_\_\_\_\_ Search Report, dated \_\_\_\_\_, which issued during the prosecution of \_\_\_\_\_ Application No. \_\_\_\_\_ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: December 6, 2006

Respectfully submitted,

By 

Irina E. Vainberg

Registration No.: 48,008

DARBY & DARBY P.C.

P.O. Box 5257

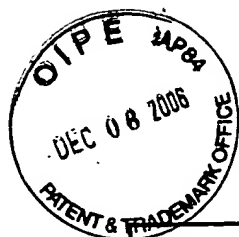
New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant





PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/903,665-Conf. #3102
				Filing Date	July 13, 2001
				First Named Inventor	Giancarlo Santus
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	04266/1006895-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA*	US-4,919,939	04-24-1990	Baker	
	AB*	US-4,994,439	02-19-1991	Longenecker et al.	
	AC*	US-5,049,386	09-17-1991	Eppstein et al.	
	AD*	US-5,091,182	02-25-1992	Ong et al.	
	AE*	US-5,143,731	09-01-1992	Viegas et al.	
	AF*	US-5,855,907	01-05-1999	Peyman	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO-90/001322	02-20-1990	Hussain, et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA	Rubin, M.D. et al Comparison Long-Term Safety of Ketorolac Tromethamine and Aspirin in the Treatment of Chronic Pain.Pharmacotherapy (1990) 10(6pt. 2) pg. 106S-110S			
	CB*	Santus, et al., Nasal Formulations of Ketorolac Tromethamine Technological Evaluation- Bioavailability and Tolerability in Rabbits, IL Farmaco, 48 (12), 1709-1723; 1993			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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